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PATENT  
Attorney Docket No. ONV-058.01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Lu, et al.

Serial No.: 09/499,526

Filing Date: February 10, 2000

For: Methods and Reagents for Treating Glucose  
Metabolic Disorders

Customer Number: 25181



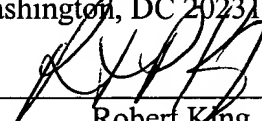
Art Unit: 1647

Examiner: R. DeBerry

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**CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)**

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Commissioner for Patents, Washington, DC 20231, on January 16, 2001.

  
Robert King

Commissioner for Patents  
Washington, D.C. 20231

Sir:

**RESPONSE TO RESTRICTION REQUIREMENT**

In response to the Restriction Requirement dated December 14, 2000, Applicants provisionally elect with traverse the invention set forth in Group IV, including claims 13-23, 28-33, 39, 42, 43, 45, 46, 50 as well as new claims 51 and 52. The claims of this

group are drawn, for example, to methods “for altering the differentiated state of a pancreatic islet or cell”, “for modifying glucose metabolism in an animal”, “for treating a disease associated with altered glucose metabolism”, “for obtaining functional pancreatic beta cells”, and “for maintaining normal pancreatic islet function” all of which comprise administering a composition comprising a PYY Therapeutic. New claims 51 and 52 are dependent claims presented in the Preliminary Amendment provided herewith.

In the restriction requirement under 35 U.S.C. § 121, the Examiner alleges that there are twenty-five distinct inventions. Group IV is presented by the Examiner as follows:

“IV. Claims 13-23, 28-33, 39, 42, 43, 45, 46, 50 drawn to a method for administering PYY Therapeutic, classification depends on structure of PYY Therapeutic.”

Applicants respectfully traverse this restriction to twenty-five groups. The Examiner’s attention is directed to M.P.E.P. § 803, which states that: “If the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions.” Thus, for a restriction requirement to be valid, the Examiner must establish the following two criteria:

- (1) the existence of independent and distinct inventions (35 U.S.C. § 121); and
- (2) that the search and examination of the entire application cannot be made without serious burden (M.P.E.P. § 803).

Applicants respectfully submit that the Examiner has not shown that the second requirement has been met with respect to the Groups above. Applicants contend that the searches required for claims drawn to various PYY-related compounds would substantially overlap and would not require an undue search burden. Therefore, it is Applicant's position that the restriction requirement is in error and that the Examiner has not shown that a serious burden would be required to examine all the claims.

Applicants note that new claims 51 and 52 depend from claim 13 of group IV and comprise administering a composition comprising a PYY Therapeutic. Accordingly, Applicants suggest that claims 51 and 52 are properly included within group IV.

In addition, the Examiner contends that “(t)erms such as ‘PYY agonist’ and ‘PYY Therapeutic, among others, are undefined.’

Applicants disagree and note that these terms are defined throughout the specification. For example, at page 4, lines 34-37, the specification reads:

In one aspect the invention comprises a method for altering the differentiation state of pancreatic islet cells, comprising administering...a PYY peptide or PYY agonist of (e.g., which mimics or enhances) PYY activity, collectively referred to herein “PYY Therapeutic”.

In conclusion, Applicants request reconsideration and withdrawal of this Restriction Requirement.


CONCLUSION:

If there are any fees in connection with the filing of this Response to Restriction Requirement, please charge the fees to our **Deposit Account No. 06-1448**. If a fee is required for an extension of time under 37 C.F.R. §1.136, such an extension is requested and the fee should also be charged to our Deposit Account. Please note that Applicants claim Small Entity Status, and any fees should be charged accordingly.

Respectfully submitted,

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Dated: January 16, 2001

  
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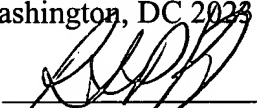
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Sir:

**PRELIMINARY AMENDMENT**

Prior to examination of the merits, please amend the claims as follows:

**IN THE CLAIMS:**

Please add new claims 51 and 52.